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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/300,959	04/27/99	ZANETTI M	P-ZA-3519

HM12/0621

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EXAMINER	
STROUP, C	
ART UNIT	**PAPER NUMBER**
1633	7

DATE MAILED: 06/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/300,959	Zanetti
Examiner	**Group Art Unit**
Stroup, Carrie	1633

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-33* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-33* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Application No.:09/300,959

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

A complete response to the instant Official action must include both a response to the notice for compliance to the sequence rules, as well as an election pursuant to the restriction set forth below.

Election/Restriction

The restriction requirement issued in Paper 5, filed 7/29/00, has been withdrawn in favor of the following restriction.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1, 2, and 5-17, drawn to a method of stimulating an immune response by administering a nucleic acid molecule encoding epitopes which may fuse with a cytokine, classified in class 514, subclass 44.

   II. Claims 3, 4, 18-21, and 29-32, drawn to a nucleic acid molecule and its use in a method of stimulating an immune response, and a method of treating a condition utilizing hematopoietic cell expression elements operationally linked to nucleic acid sequence encoding epitopes or

heterologous polypeptides which may be expressed as fusion with a cytokine, classified in class 435, subclass 343.1.

III. Claims 22-28, and 33, drawn to a nucleic acid molecule and it use in a method of treating a condition comprising a hematopoietic cell expression element operationally linked to nucleic acid sequence encoding an immunoglobulin molecule, classified in class 435, subclass 327.

IV. Claim 33, drawn to a method of treating a condition comprising a hematopoietic cell expression element operationally linked to a nucleic acid sequence encoding a hormone, classified in class 536, subclass 23.51.

V. Claim 33, drawn to a method of treating a condition comprising a hematopoietic cell expression element operationally linked to a nucleic acid sequence encoding a clotting factor, classified in class 536 , subclass 23.53.

Applicant is advised that where a single claim encompases more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups II and III are drawn to materially different structures. For example, the invention of group II is drawn to a nucleic acid molecule encoding a hematopoietic cell expression element operationally linked to a nucleic acid sequence encoding heterologous polypeptide, such as one which fuses with a cytokine, while the invention of group III is drawn to a nucleic acid molecule comprising an expression element operationally linked to a nucleic acid sequence encoding an immunoglobulin.

3. The inventions of groups I-V are drawn to materially different methods. For example, the invention of group I is drawn to a method of stimulating an immune response by administering to lymphoid tissues a nucleic acid molecule; the invention of group II requires the utilization of a hematopoietic expression element operationally linked to a nucleic acid sequence encoding one or more heterologous epitopes; the invention of group III is to a method of treating a condition by administering a nucleic acid molecule comprising a hematopoietic cell expression element operationally linked to a nucleic acid sequence encoding an immunoglobulin; and the invention of group IV is drawn to a method of treating a condition by administering a nucleic acid molecule comprising a hematopoietic cell expression element operationally linked to a nucleic acid sequence encoding a clotting factor.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I and II-IV are unrelated, and inventions V and II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid molecules of group II cannot be used with the methods of groups I, III, or IV, and the nucleic acid molecules of group III cannot be used with the methods of groups I, II, and IV.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classifictions, recognized divergent subject matter and further because the searches required for the different inventions are not coextensive, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Stroup whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached at (703) 308-0294. The fax phone number for this Group is (703) 308-8724.

Carrie Stroup

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